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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,234	03/15/2007	Stefan Golz	004974.01210	2203

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EXAMINER	
BALLARD, KIMBERLY	
ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,234	GOLZ ET AL.	
	Examiner	Art Unit	
	Kimberly Ballard	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 21-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18 and 21-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. Claims 1-12, 18, and 21-23 have been amended and claims 19-20 and 24-26 have been cancelled as requested in the Preliminary amendment filed August 3, 2006. Following the amendment, claims 1-18 and 21-23 are pending in the instant application.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 and 4-11, drawn to a method of screening for therapeutic agents comprising contacting a test compound with a KLKB1 polypeptide and detecting binding of said test compound to said KLKB1 polypeptide.

Group II, claim(s) 2-3, drawn to a method of screening for therapeutic agents comprising determining activity of a KLKB1 polypeptide at several different concentrations of a test compound.

Group III, claim(s) 12-17, drawn to a method of screening for therapeutic agents comprising contacting a test compound with a KLKB1 polynucleotide and detecting binding of said test compound to said KLKB1 polynucleotide.

Group IV, claim(s) 18, drawn to a method of diagnosing a disease, comprising determining the amount of a KLKB1 polynucleotide in a sample taken from a mammal.

Group V, claim(s) 21, in part, drawn to a pharmaceutical composition comprising a therapeutic agent which regulates the activity of a KLKB1 polypeptide, wherein the therapeutic agent is a small molecule.

Group VI, claim(s) 21, in part, and claim 22 in full, drawn to a pharmaceutical composition comprising a therapeutic agent which regulates the activity of a KLKB1 polypeptide, wherein the therapeutic agent is a polynucleotide.

Group VII, claim(s) 21, in part, and claim 23 in full, drawn to a pharmaceutical composition comprising a therapeutic agent which regulates the activity of a KLKB1 polypeptide, wherein the therapeutic agent is a KLKB1 polypeptide.

Group VIII, claim(s) 21, in part, drawn to a pharmaceutical composition comprising a therapeutic agent which regulates the activity of a KLKB1 polypeptide, wherein the therapeutic agent is an antibody.

Group IX, claim(s) 21, in part, drawn to a pharmaceutical composition comprising a therapeutic agent which regulates the activity of a KLKB1 polypeptide, wherein the therapeutic agent is a ribozyme.

3. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-IX appears to be that they all relate to an agent which binds to or modulates the activity of a KLKB1 polypeptide or KLKB1 polynucleotide, such as for detection of the polypeptide or polynucleotide for diagnostics or for screening for therapeutic agents. However, US 2003/0087316 A1 by Hugli et al. (published May 8, 2003; cited on IDS) teaches methods for detecting, diagnosing, and monitoring liver damage in a subject comprising the detection of kallikrein (i.e., KLKB1) (see abstract). Hugli et al. teach a series of detection reagents that are specific for each member of a live damage panel, which includes a reagent for detection of kallikrein (see [0020]). Further, Hugli et al. disclose methods for screening a therapeutic agent for toxicity, comprising determining the level of kallikrein in an *in vitro* assay after incubating cultured cells in the presence of the therapeutic agent (see [0021]). Thus, the technical feature linking the inventions of Groups I-IX does not constitute a special technical

feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Election of Species

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

DISEASES

A) Cardiovascular disorders

B) Endocrine system and hormone disorders

C) Metabolic diseases

D) Gastrointestinal and liver diseases

E) Inflammatory disease

F) Cancer disorders

G) Muscle-skeleton disorders

H) Neurological disorders

I) Urological disorders

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-3, 12, 18, 21-23.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The different diseases and disorders comprise a diverse spectrum of medical disorders that are unique in terms of their diagnosis, etiology, pathology, and affected populations and therefore the different species do not relate to a general inventive concept under PCT Rule 13.1.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

6. The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does

not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Ballard whose telephone number is 571-272-2150. The examiner can normally be reached on Monday-Friday 9 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Elizabeth C. Kemmerer/
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